

## PATENT COOPERATION TREATY

ANKOM

2005-03-18

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) 17-03-2005

Applicant's or agent's file reference

AH53722

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/SE 2004/001879

International filing date (day/month/year)

15.12.2004

Priority date (day/month/year)

15.12.2003

International Patent Classification (IPC) or both national classification and IPC

A61M 25/10, A61M 16/04, A61L 2/16

Applicant

Nitricare KB et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further opinions, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/SE 2004/001879

**Box No. I      Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language, \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format  
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 18-39, 51-53

because:

- ☒ the said international application, or the said claims Nos. 18-39, 51-53  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See PCT Rule 67.1.(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ The claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for said claims Nos. \_\_\_\_\_
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of  
the Administrative Instructions in that:
- |                            |  |
|----------------------------|--|
| the written form           | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not  
comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.
- ☐ See Supplemental Box for further details.

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-17, 40-50	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-17, 40-50	NO
Industrial applicability (IA)	Claims	1-17, 40-50	YES
	Claims		NO

2. Citations and explanations:

The following documents are cited in the International Search Report:

D1: US 5417657 A1

D2: S. Carlsson, N.P. Wiklund, L. Engstrand, E. Weitzberg, J.O.N. Lundberg, "Effect of pH, Nitrite and Ascorbic Acid on Nonenzymatic Nitric Oxide Generation and Bacterial Growth in Urine", NITRIC OXIDE: Biology and Chemistry, Vol. 5, No. 6, (2001), pp. 580-586

D3: WO 8401721 A1

The present application pertains to a device and a method for reducing the risk of infections acquired during hospital treatment, so called nosocomial infections, which arise after the insertion of catheters, intratracheal tubes and similar devices into a human or animal body. The device has an expandable part to keep it in place and releases at least one low molecular antimicrobial compound (LMAC) which penetrates through the device and exerts antimicrobial action on the surroundings.

D1 (column 3 line 5-22, column 4 line 31-49, claim 1) describes a urinary catheter comprising a microporous balloon which releases drugs to kill and prevent bacterial growth in and around the urinary bladder.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.  
Continuation of: Box V

D1 is considered to be the document which represents the closest prior art. Claims 1-6, 9-16, 40, 41 and 44-49 differ from D1 in that a low molecular drug, i.e. a low molecular antimicrobial compound (LMAC), is used as the drug. The LMAC may be reactive nitrogen- or oxygen intermediates. The LMAC may be released by nitrite in an acidic or basic environment and ascorbic acid may be used in combination with nitrite.

The problem solved by the present invention is therefore considered as finding compounds that are reactive nitrogen- or oxygen intermediates. The compound may be released by nitrite in an acidic environment where the reactive nitrogen- or oxygen intermediates have antimicrobial action.

D2 describes an investigation concerning the effect of pH, nitrite and ascorbic acid on bacterial growth in urine (see abstract). According to D2, it is possible to release reactive nitrogen intermediates by acidifying urine containing nitrite, see page 582, column 2 lines 1-22.

What is described in document D2 is considered as having the same advantages as the present application. It is thus considered obvious to the person skilled in the art to include this "part" in the device which is described in document D1 to solve the present problem. The invention according to claims 1-6, 9-16, 40, 41 and 44-49 is thus considered to lack inventive step.

Claims 7, 8, 42 and 43 differ from D1 and D2 in that devices other than catheters, which can be inserted into the body are mentioned. The description in the present application only has examples comprising catheters. It is considered as obvious to the person skilled in the art to adapt what is known from D1 and D2 for use in other devices which are inserted into the body. The invention according to claims 7, 8, 42 and 43 is thus considered to lack inventive step.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.  
Continuation of: Box V

The invention according to claim 17 differs from D1 and D2 because metal ions are present in the device for insertion into the body. The metal ions contribute to increasing the antimicrobial effect. In claim 50 zinc is used in combination with nitrite and ascorbic acid.

D3 describes a method where zinc is known to be used as an antimicrobial metal in catheters, see abstract and page 4. It is considered as obvious to the person skilled in the art to use what is known from D3 to attain the invention according to claims 17 and 50. The invention according to claims 17 and 50 thus lacks inventive step.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 2004/001879

## A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 25/10, A61M 16/04, A61L 2/16

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M, A61L, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5417657 A (CAROLYN HAUER), 23 May 1995 (23.05.1995), column 3, line 5 - line 22; column 4, line 31 - line 39, claim 1 --	1-53
Y	S. CARLSSON ET AL, "Effects of pH, Nitrite, and Ascorbic Acid on Nonenzymatic Nitric Oxide Generation and Bacterial Growth in Urine", NITRIC OXIDE: Biology and Chemistry, 2001, Vol. 5, No. 6, p 580-586, ISSN 1089-8603, page 582, column 2, line 1 - line 22, abstract --	1-16,18-49, 51-53
A		17,50

☒ Further documents are listed in the continuation of Box C.
 ☒ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

15 March 2005

Date of mailing of the international search report

17-03-2005

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## INTERNATIONAL SEARCH REPORT

International application No.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 8401721 A1 (BAXTER TRAVENOL LABORATORIES, INC.), 10 May 1984 (10.05.1984)	17,50
A	---	1-16,18-49, 51-53
A	US 20020082221 A1 (ROBERT A. HERRMANN ET AL), 27 June 2002 (27.06.2002)	1-53
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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/SE 2004/001879

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 18-39, 51-53  
because they relate to subject matter not required to be searched by this Authority, namely:  
Claims 18-39 and 51-53. relate(s) to a method of treatment of the human or animal body by surgery or by therapy, as well as diagnostic methods /Rule 39.1(iv). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the device.
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

01/03/2005

International application No.

PCT/SE 2004/001879

US	5417657	A	23/05/1995	NONE		
WO	8401721	A1	10/05/1984	AU	2039883 A	22/05/1984
				CA	1224717 A	28/07/1987
				EP	0124536 A	14/11/1984
				ES	527051 A	01/05/1985
				ES	8504464 A	16/07/1985
				US	4603152 A	29/07/1986
US	20020082221	A1	27/06/2002	CA	2443080 A	25/07/2002
				EP	1343485 A	17/09/2003
				JP	2004523520 T	05/08/2004
				US	6780849 B	24/08/2004
				US	20040259840 A	23/12/2004
				WO	02056874 A	25/07/2002